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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,269	01/14/2004	George M. Halow	A-8051.CIP.RNFMP/bh	2686

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EXAMINER	
CHOI, FRANK I	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 02/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/756,269	HALOW, GEORGE M.	
	Examiner	Art Unit	
	Frank I. Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claims 42-53 are objected to because of the following informalities: "inbalance" should be "imbalance". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 42-53 recites the limitation "no supplemental electrolytes for counteracting patient electrolyte imbalance". There is insufficient antecedent basis for this limitation in the claims in that claim 1 and claim 13 requires the presence of sodium phosphates which are electrolytes. Applicant has not shown that the phrase "for counteracting patient electrolyte imbalance" excludes sodium phosphates. Examiner suggests that Applicant amend claims 42-53 to indicate that other than the sodium phosphates there are no supplemental electrolytes.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/43654 in view of Wood et al. (US Pat. 5,498,425) and Vining (US Pat. 5,782,762) in further view of Kaori et al. and Physician's Desk Reference (49th Ed. 1995).

WO 98/43654 teach a composition and method of purging the colon prior to colonoscopy, radiographic examination or bowel surgery containing sodium phosphate salts, including mono and dibasic salts) combined with polyethylene glycol, bisacodyl and cascara sagrada and that the composition can be administered in solid or liquid (aqueous) form (Pgs. 1, 7, 11). It is taught the combination of compounds are present in amounts effective to produce a purgative and/or laxative composition which evidences synergistic activity and that one of ordinary skill in the art may readily determine the amount and types of compounds/compositions to used in treating a particular patient (Pg. 11).

Wood et al. ('425) teach that cascara and bisacodyl are used for bowel clearance. It is taught that powders may be packaged in aluminum lined paper containers and that such packets are economical and easier to ship and store (Column 1, lines 6-12, Column 3, lines 4-7).

Vining teaches that in addition to using laxatives the patient should be put on a clear liquid diet to obtain a clean bowel for examination (Column 8, lines 1-20).

Kaori et al. disclose the combination of 45 ml of oral sodium phosphate (Fleet®) mixed with 45 ml of water and 1000 ml of PEG electrolyte lavage which was tolerated well and resulted in satisfactory cleansing of the colon (Abstract). It is disclosed that this modified method using smaller amount of oral lavage is useful in the preparation for colonoscopy (Abstract).

Physician's Desk Reference (1995) discloses that 5 ml of regular or flavored Fleet ® Phospho®-soda contains 2.4 g or monobasic sodium phosphate and .9 g of dibasic sodium phosphate and that 45 ml is used as a purgative (Pgs. 1018, 1019). It is disclosed that Golytely®,

PEG-3350 and electrolytes for oral solution contain 236 grams of PEG-3350 which is in powder form to be reconstituted with 4 liters of water (Pg. 657).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the combination sodium phosphate and PEG for use as a bowel cleanser. However, the prior art amply suggests the same as the prior art discloses the combination of PEG and sodium phosphate for use as a bowel cleanse. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the combination would be effective as a bowel cleanser for use in clearing bowel prior to examination procedures and is well tolerated.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

There is no indication in the study that the test subjects received a dose of Fleet ® the night before the procedure. Applicant argument is insufficient to establish the same. Applicant argues that there is no indication that Golytely ® was used, however, in view of the references cited in the Matsuoka et al. reference, it is apparent that Golytely ® was used in the experiment. Further, Golytely® and NuLytely ® require reconstitution with 4 liters of water, however, the actually amount given can be less then 4 liters.

With respect to Applicant's evidence of non-obviousness, the fact that six patients had virtually no complaints is insufficient to overcome the rejection. At least six patients in the prior art study had no complaints.

Contrary to Applicant the motivation to combine the references is clear. The prior art discloses that combination of sodium phosphate and PEG are effective in gastric lavage and exhibit reduced side effects. Further, it is well within the skill of and one of ordinary skill in the

art to combine several methods of bowel clearance as desired to achieve the level of bowel clearance necessary.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Claims 1-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/43654 in view of Cleveland et al. (US Pat. 6,048,901), Wood et al. (US Pat. 5,498,425) and Vining (US Pat. 5,782,762) in further view of Sobrino-Faya et al. and Physician's Desk Reference (49th Ed. 1995).

WO 98/43654, Wood et al. (US Pat. 5,498,425) and Vining (US Pat. 5,782,762) are cited for the same reasons as above and are incorporated herein to avoid repetition.

Cleveland et al. teach that polyethylene glycol is effective in reducing intestinal gases, cramping and/or anorectal irritation associated with constipation and which can be exacerbated by use of laxatives (Column 1, lines 14-30). It is taught that the composition is preferably substantially free of ancillary electrolytes as salts may exert a constipative effect (Column 45-58). It is taught that the PEG polymer used is solid at room temperature and soluble with water and may be mixed with water or juice (Column 1, lines 58-68, Column 2, lines 1-20).

Sobrino-Faya et al. discloses the combination of 90 ml of a standard preparation of sodium phosphate with 1500 ml of PEG and that colonic cleansing tended to be better sodium phosphate and PEG versus sodium phosphate alone (Abstract).

Physician's Desk Reference (1995) discloses that 5 ml of regular or flavored Fleet ® Phospho®-soda contains 2.4 g or monobasic sodium phosphate and .9 g of dibasic sodium phosphate and that 45 ml is used as a purgative (Pgs. 1018, 1019).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the combination sodium phosphate and PEG for use as a bowel cleanser. However, the prior art amply suggests the same as the prior art discloses the combination of PEG and sodium phosphate for use as a bowel cleanse. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the combination would be effective as a bowel cleanser for use in clearing bowel prior to examination procedures, the combination with PEG would reduce any intestinal gas or cramping which may be exacerbated by use of laxatives, that lack of ancillary salts would increase laxative effect due to reduced constipation and that the combination of PEG and sodium phosphate would be effective cleansing the colon for colonoscopy.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Further, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references

would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Contrary to Applicant arguments, there is no mention of Golytely® in the rejection herein and Examiner has not relied on the PDR disclosure for Golytely ®. The PDR is only cited for its teachings of Fleet ®.

As indicated above, there is no requirement that Sobrino-Faya disclose the make up of the PEG described in the article or disclose the use of powders. Further, it is well within the skill of to vary concentrations and amounts depending on desired efficacy, i.e. cleansing of the bowel. Cleveland discloses reconstitution of solid PEG. The reason to combine Wood et al. and Vining is clear as indicated above. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. In re Linter, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972); In re Dillon, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990), cert. denied, 500 U.S. 904 (1991).

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-53 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30, 32, 33 of copending Application No. 10/194251. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims 1-30, 32,33 of the '251 application anticipate claims 1-36, 42-53 of the present Application in that the '251 application claims amount ranges of the same components which fall within the ranges in the present application. Claims 37-41 are obvious of the claims of the '251 application in that the '251 application discloses amount ranges of the sodium phosphates and amount ranges of PEG which falls within the range of the PEG in the present claims. The difference between the claims of '251 application and the claims of the present invention is that the PEG is water-soluble and in a dry dosage form which is subsequently dissolved in water for use, whereas the claims of the present Application claim a PEG which liquid at room temperature and is in a liquid dosage form which optionally can be combined with an aqueous medium. However, it is well within the skill of one ordinary skill in the art to modify the prior art as above with the expectation that when the '251 application composition is dissolved in an aqueous medium for use, the PEG contained therein will be liquid at room temperature. As such, claims 37-41 are an obvious modification of the claims of the '251 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FIC
February 6, 2006

JOHN PAK
PRIMARY EXAMINER
GROUP 1600